IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/642,587	Confirmation No.:	2933
Applicants	:	S. BOGOCH		
Filed	:	19 August 2003		
Title	:	AGLYCO PRODUCTS AND METHODS OF USE		
Art Unit	:	1649		
Examiner	:	Gregory S. EMCH		
Docket No.	:	13793/468031 (formerly 09425/468031)		
Customer No.	:	23838		

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT OF SUBSTANCE OF INTERVIEW AND SUPPLEMENTAL RESPONSE UNDER § 1.111

Dear Sir:

This is a statement of the substance of the Interview of November 20, 2007 ("the Interview") and a Supplemental Response to the Office Action of September 24, 2007. The Supplemental Response supplements the Response to Final Office Action with RCE filed October 31, 2007.

The Interview of November 20, 2007 encompassed arguments in response to the Office Action mailed September 24, 2007. Applicants respectfully submit the arguments made herein respond to the rejections made in the Office Action and reflect the discussion and suggestions provided by Examiner Emch and Supervisory Patent Examiner Chan during the Interview.

Applicants express their gratitude to Examiner Emch and Supervisory Examiner Chan for their time during the Interview, which Applicants' representatives found most helpful and productive. Applicants provide herein the substantive arguments presented by Applicants' representatives at the Interview and requested by Examiner Emch and Supervisory Patent Examiner Chan.

Remarks begin on page 2 of this paper.
Statement of Substance of the Interview begins on page 3 of this paper.

REMARKS

Claims 13, 15 and 24-27 and 32 are pending. Claims 1-12, 14, 16-23 and 28-31 are canceled. No claims are herein amended or added.

In the Final Office Action mailed September 24, 2007, the Examiner has continued to find claims 15 and 24-27 allowable. The Examiner has maintained, however, the rejection of claim 13 for obviousness-type double patenting over U.S. Patent Nos. 4,298,590 and 4,486,538 (based on inherency) and for inherent anticipation over U.S. Patent No. 4,486,538. The Office alleges U.S. Patent 4,486,538 inherently anticipates claim 13 (even though the patent does not teach or direct the skilled artisan to an antibody that binds to the SEQ ID NO: 2 epitope of malignin) because the patent teaches antimalignin antibodies that bind quickly (in about 10 minutes) to malignin and antimalignin antibodies that bind slowly (in about 2 hours) to malignin and this fast- and slow-binding phenomenon was also observed upon inoculation of rabbit with SEQ ID NO:2. Additionally, the Office alleges claims 12-14 of U.S. Patent No. 4,298,590 render claim 13 obvious because an antimalignin antibody of claims 12-14, while not directed to the SEQ ID NO:2 epitope of malignin, is nevertheless directed to the about 89 amino acid residue malignin peptide, which contains the 12 amino acid SEQ ID NO:2 epitope.

It is noted that an Information Disclosure Statement is submitted simultaneously herewith, consideration of which is respectfully requested.

STATEMENT OF SUBSTANCE OF THE INTERVIEW

Participants at the Interview were Examiner Emch, Supervisory Examiner Chan, Richard Ward of Kenyon & Kenyon LLP and Daren P. Nicholson of Replikins LLC. During the Interview, the disclosure and claims of U.S. Patent No. 4,486,538 and the claims of U.S. Patent No. 4,298,590 were discussed.

The participants discussed that U.S. Patent No. 4,486,538 does not disclose or suggest the SEQ ID NO: 2 epitope on the malignin oncoprotein. The participants further discussed that U.S. Patent No. 4,486,538, in fact, discloses no sequences of any kind related to the about 89 amino acid malignin oncoprotein peptide. The participants further discussed that the cited patents do not identify epitopes on the malignin oncoprotein peptide and disclose no epitope sequences whatsoever. The participants also discussed that claims 12-14 of U.S. Patent No. 4,298,590 do not reference, claim or contain an element of an epitope on the malignin oncoprotein peptide and do not reference, claim or contain an element of SEQ ID NO: 2.

Applicants provided additional evidence that fast-binding antimalignin antibody species and slow-binding antimalignin antibody species disclosed in U.S. Patent 4,486,538 are not necessarily the same as antibodies to SEQ ID NO:1 and SEQ ID NO:2 in the above-captioned application. Applicants noted that two epitopes on the malignin peptide are disclosed in the above-captioned application, namely SEQ ID NO: 1 and SEQ ID NO: 2. Applicants further noted that no obvious homology exists between these two identified epitopes. Nevertheless, inoculation of rabbits with SEQ ID NO:1 produced both a fast-binding and a slow-binding anti-SEQ ID NO:1 antibody (see Figures 9A and 9B) and inoculation of rabbits with SEQ ID NO:2 produced both a fast-binding and a slow-binding anti-SEQ ID NO:2 antibody (see Figures 8A and 8B).

A. Fast- and slow-binding antibodies in cited patents not directed to particular epitopes on malignin peptide

In U.S. Patent 4,486,538, two "species" of antimalignin antibody are disclosed, namely a fast-binding species of antimalignin antibody and a slow-binding species of antimalignin antibody. Col. 2, ll. 21-69. The fast-binding species binds in about 10 minutes. The slow-binding species binds in about two hours. Both the fast- and slow-binding species are disclosed

as present in the serum of human cancer patients, induced in mice by inoculation with malignin, and produced monoclonally from separate myeloma cell lines. *Id.* As discussed above, there is no disclosure in the patent concerning where on the malignin peptide these fast- and slow-binding species of antimalignin antibody might be attaching. Nevertheless, inoculation with the intact whole malignin peptide (about 89 amino acid residues) resulted in production of both fast- and slow-binding species of antimalignin antibody.

B. SEQ ID NO:1 and SEQ ID NO:2 epitopes both induce fast- and slow-binding antibodies

In the above-captioned application, Applicants identified two epitopes on the malignin peptide, namely SEQ ID NO: 1 and SEQ ID NO: 2. Appln. at 22-26, Example 6. An exhaustive investigation of the total number and position of epitopes on the malignin peptide was not undertaken. As such, one of skill in the art would not expect that SEQ ID NO: 1 and SEQ ID NO: 2 were the only epitopes on the malignin peptide. *See, e.g.,* Geysen *et al.*, Use of peptide synthesis to probe viral antigens for epitopes to a resolution of a single amino acid, PNAS USA, Vol. 81, pp. 3998-4002, July 1984 Biochemistry at 4001, left column ("different animals do not necessarily respond to all of the epitopes on a given antigen").

As identified by Applicants, the 16 amino acid SEQ ID NO: 1 and the 12 amino acid SEQ ID NO: 2 do not share significant homology. *See, e.g.,* Appln. at Appln. at 22, ll. 6-7. As such, one of skill in the art would expect different antibodies to be produced to these different epitopes.

In two inoculations of rabbit with SEQ ID NO: 1, both a species of fast-binding anti-SEQ ID NO: 1 antibody and a separate species of slow-binding anti-SEQ ID NO: 1 antibody were observed. See Figures 9A and 9B. Likewise, in two inoculations of rabbit with SEQ ID NO: 2, both a species of fast-binding anti-SEQ ID NO: 2 antibody and a species of slow-binding anti-SEQ ID NO: 2 antibody were observed. See Figures 8A and 8B. Since SEQ ID NO:1 and SEQ ID NO:2 do not share significant homology, one of skill in the art would expect that as many as four different species of antimalignin antibody were produced in Figures 8A, 8B, 9A and 9B. The first species would be fast-binding anti-SEQ ID NO: 1 antibody, the second species would be slow-binding anti-SEQ ID NO: 1 antibody, the third species would be fast-binding anti-SEQ ID NO: 2 antibody, the fourth species would be slow-binding anti-SEQ ID NO: 2 antibody.

One of ordinary skill in the art would understand from these observations that the fast- and slow-binding antibody species disclosed in U.S. Patent 4,486,538 were not necessarily an anti-SEQ ID NO:1 fast- or slow-binding antibody or an anti-SEQ ID NO:2 fast- or slow-binding antibody. Instead, one of ordinary skill in the art would understand that fast- and slow-binding antibody species might be induced to any one of the myriad of possible epitopes on the about 89 amino acid residue whole malignin peptide. One of ordinary skill in the art would conclude that even though fast- and slow-binding antibodies to the whole malignin peptide were produced and disclosed in U.S. Patent 4,486,538 and a form of such antibodies was claimed in U.S. Patent No. 4,298,590, fast- and slow-binding antibodies that bind specifically to the SEQ ID NO: 1 or SEQ ID NO: 2 epitopes on the malignin peptide were not disclosed and were not necessarily produced in the disclosure and claims of those cited patents.

C. Fast- and slow-binding antibodies in cited patents are not necessarily directed against the SEQ ID NO:1 or SEQ ID NO:2 epitopes on the malignin peptide

Because fast- and slow-binding antibodies were separately produced against SEQ ID NO:1 and SEQ ID NO:2 and a lack of homology between SEQ ID NO:1 and SEQ ID NO:2 suggests that different antibodies were produced to these different epitopes, one of skill in the art would expect that fast- and slow-binding antibodies to the entire malignin peptide (about 89 amino acid residues) would not necessarily be the same antibody as the fast- and slow-binding antibodies produced against SEQ ID NO:2 (12 amino acid residues) or as the fast- and slow-binding antibodies produced against SEQ ID NO:1 (16 amino acid residues). One of ordinary skill in the art would be expected to conclude, therefore, that the "two constituent species of antibody" recognized in column 2, lines 19-35 of U.S. Patent No. 4,486,538 were not necessarily antibodies that bind specifically to SEQ ID NO: 2 as claimed in claim 13 of the above-captioned application.

As requested in the Interview and acknowledged by Examiner Emch and Supervisory Examiner Chan, Applicants respectfully request the rejection of claim 13 be withdrawn in view of the evidence that an antibody that binds specifically to SEQ ID NO: 2 was not necessarily produced by the fast- and slow-binding antibody species disclosed and claimed in U.S. Patent Nos. 4,486,538 and 4,298,590.

CONCLUSION

It is believed that the present claims are in conditions for allowance and Applicants earnestly request the same. Any fee that the Commissioner determines necessary for entry of the instant paper are hereby authorized to be charged to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

The Examiner is invited to contact the undersigned attorney if necessary to expedite allowance. An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

KENYON & KENYON LLP

Dated: December 14, 2007

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